Patient Education and Counseling xxx (2018) xxx–xxx

Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.elsevier.com/locate/pateducou

Review article

Best-practices for the design and development of prescription medication information: A systematic review

Rebecca J. Mullen[a,*], James Duhig[c], Andrea Russell[a], Linda Scarazzini[c], Fabio Lievano[b], Michael S. Wolf[a]

[a] Division of General Internal Medicine and Geriatrics, Feinberg School of Medicine, Northwestern University, 750 N. Lake Shore Drive, 10th Floor, Chicago, IL, 60611, United States
[b] Safety Sciences, AbbVie, Inc., 1 N. Waukegan Rd., GM60, AP51-2, North Chicago, IL, 60064, United States
[c] Pharmacovigilance and Patient Safety, AbbVie, Inc., 1 N. Waukegan Rd., GM60, AP51-2, North Chicago, IL, 60064, United States

ARTICLE INFO

Article history:
Received 11 September 2017
Received in revised form 10 February 2018
Accepted 7 March 2018

Keywords:
Prescription medications
Labeling
Education
Benefit/risk

ABSTRACT

Objective: To present evidence supporting best-practices for prescription drug labeling and educational materials.
Methods: Articles were selected from three online databases (PubMed, Embase, CINAHL). Eligible manuscripts were: 1) English-language, 2) randomized, controlled trials, and 3) focused on improving prescription drug labeling practices.
Results: Forty-nine articles were reviewed, and included both regulated label materials and pharmacy or health systems-generated tools. Best-practices included use of plain language principles, typographic cues, quantitative descriptors, and standardized formats, when applicable. Common outcomes included preference and comprehension, while few studies examined actual medication use (e.g. adherence, harms) or clinical health outcomes. Approximately half of studies directly engaged patients' perspectives in intervention development, which may have helped increase tool effectiveness.
Conclusions: Several best practices were apparent in the literature, particularly for written materials and pharmacy-generated container labeling. Design principles for supplemental instructions and multimedia tools were less cohesive, albeit less researched. The impact of patient involvement in tool design is promising, though requiring further study.
Practice implications: Definitive studies to inform practice standards on how to best communicate medication information to consumers are needed, especially as communication modalities continue to evolve. Increased research on if and how to incorporate patient-centered decision-making into the development process should be considered.

Contents

* Corresponding author at: Northwestern University Feinberg School of Medicine Division of General Internal Medicine and Geriatrics 750 N. Lake Shore Dr., 10th Floor Chicago, IL 60611, United States.
E-mail addresses: r-mullen@northwestern.edu (R.J. Mullen), james.duhig@abbvie.com (J. Duhig), andrearussell2021.1@u.northwestern.edu (A. Russell), linda.scarazzini@abbvie.com (L. Scarazzini), leviano@abbvie.com (F. Lievano), mswolf@northwestern.edu (M.S. Wolf).

https://doi.org/10.1016/j.pec.2018.03.012
0738-3991/

1. Introduction

Expansive evidence has indicated that consumers lack adequate understanding of their prescription medications, which can lead to medication errors, adverse drug events (ADEs) or suboptimal treatment benefits. Numerous seminal reports have identified and targeted problems with specific aspects of prescription labeling and written information sources. In the past decade, several reviews have sought to consolidate this evidence and establish best-practices for the design of prescription medication information (PMI) [1–3]. However, these have mostly focused on either a specific aspect of written prescription labeling or type of content. As a result, it has been difficult to fully grasp the best-practices for communicating PMI in its entirety. The consequences are considerable; variable recommendations to industry and health systems have been set forth by state and government agencies globally.

An updated, comprehensive review of this literature is needed, especially in light of recent technological advances and the mounting availability of various PMI modalities. In addition, a specific emphasis on whether and how patient perspectives are addressed and/or incorporated into the design of PMI tools is also necessary, as there have been increasing regulatory, industry and health systems considerations for the value of patient involvement in various aspects of pharmaceutical development [4–8]. However, these recommendations have often been vague, resulting in continued confusion within the field regarding how to best operationalize and demonstrate patient-centeredness.

The purpose of this review was twofold: 1) provide an updated, more comprehensive review of best practices regarding the design of PMI materials, and 2) assess the role of the patient in the development of these tools. To accomplish these objectives, we reviewed randomized, controlled trials that assessed the effectiveness of PMI materials compared to standards of care in improving outcomes related to patient attitudes/preference, understanding, safe use, and adherence among users of prescribed medications. We also explored whether patient-centered principles were utilized in material development, and the possible impact of this practice on tool effectiveness.

2. Methods

2.1. Literature search and selection

This review was conducted according to PRISMA guidelines [9]. Articles were selected from three online databases (PubMed, Embase, CINAHL). Limits to the search included English language and online publication prior to 2016. Articles were also reference-mined from our initial search. Articles were eligible for inclusion if they met the following criteria: 1) human subjects research, 2) English-language, 3) conducted in the U.S., U.K. Canada, Australia or South Africa, 4) published in a peer-reviewed journal, 5) of a randomized, controlled study design, and 6) included interventions to improve information and/or educational materials for prescribed medications. Specifically, this review focused on patient-oriented informational materials. This included materials regulated by health authorities and produced by drug and device manufacturers, including patient information leaflets, patient package inserts (PPI), and Medication Guides. In addition, materials produced by pharmacies, health systems and provider organizations, including consumer medication information (CMI), pharmacy-generated container labeling and supplementary instructions were also included. Various dissemination modes, including print and multimedia, were reviewed.

Following the initial database search, study selection occurred in four phases. Two independent coders (RM, AR) conducted a title review of all articles returned from the database search and excluded any article that was clearly unrelated to the research question. Next, each coder performed an abstract review which further eliminated any articles not adhering to inclusion criteria. Disagreement between coders was resolved by a third independent coder (MW) at each of the selection phases. A full article review was then completed by one coder (RM), which identified articles for final data abstraction. Finally, a secondary search was performed using the references for all articles that were selected for data abstraction from the database search. An overview of the study selection process and search yield at each selection phase is included in Fig. 1.

Please cite this article in press as: R.J. Mullen, et al., Best-practices for the design and development of prescription medication information: A systematic review, Patient Educ Couns (2018), https://doi.org/10.1016/j.pec.2018.03.012